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10/690,600

10/23/2003

Dar-Fu Tai

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EXAMINER

LIN, JERRY

ART UNIT

PAPER NUMBER

1631

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                               |                            |  |
|------------------------------|-------------------------------|----------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>10/690,600 | Applicant(s)<br>TAI ET AL. |  |
|                              | Examiner<br>Jerry Lin         | Art Unit<br>1631           |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 September 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-12 is/are pending in the application.
- 4a) Of the above claim(s) 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Applicants' arguments, filed September 19, 2007, have been fully considered and they are deemed to be persuasive in-part. However, in light of the amendments, the following rejections are newly applied or modified as necessitated by amendment. They constitute the complete set presently being applied to the instant application.

### ***Election/Restriction***

2. Newly amended claim 12 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The originally presented claims and the amended claim 12 are directed to related processes. The related inventions are distinct if (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions have materially different design, mode of operation, function and effect. The original claims were drawn to a method for discriminating a peptide and included the step of detecting by QCM or a SPR. In contrast, amended claim 12 is drawn to forming a molecularly imprinted membrane with the intended use of discriminating a peptide. The intended use of discriminating a peptide in claim 12 is not given patentable weight as it does not, in fact, limit the claimed method steps. Thus, the invention of the original claims and the invention of the

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amended claim 12 have different purposes and have a materially different function and effect. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 12 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Status of the Claims***

Claims 1 and 3-11 are under examination.

Claim 12 is withdrawn.

The Applicant has elected the monomer N-benzylacrylamide in claim 5, the organic compound as a derivative of cystine in claims 3 and 4, the template molecules of a peptide in claims 6-8, and detection by quartz crystal microbalance in claim 1.

### ***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> Paragraph***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. Claims 1, 3-8, 10, and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter Rejection.

The applicants have amended the instant claims to include step (b), "dissolving said derivative of cystine in a mixture of acetonitrile and DMF." However, the specification, as filed, did not teach such a limitation. Rather, the specification, on page 4, teaches that (Acr-Cys-NHBn)<sub>2</sub> may be dissolved in a mixture of acetonitrile (10ml) and DMF (0.1 ml). This teaching does not provide support for the broad limitation of dissolving a "derivative of cystine" in a mixture of acetonitrile and DMF. Furthermore, other than (Acr-Cys-NHBn)<sub>2</sub>, the specification does not provide support for dissolving the various derivatives of cystine in claim 4 in a mixture of acetonitrile and DMF. Thus, the amendment is NEW MATTER.

This rejection is necessitated by amendment.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> Paragraph***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claims 1 and 3-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 3-11 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: discriminating a peptide. The instant claims are drawn to a method for forming a molecularly imprinted membrane and discriminating a peptide. The method steps include the process of making a chip, however, do not include any steps regarding how the peptide is discriminated. Claim 1 does include a step of detecting, but it does not teach what is being detected or how that detection leads to discriminating a peptide.

This rejection is maintained from the previous office action.

#### Response to Arguments

7. Applicants have responded to the instant rejection with amendments. However, as explained above, the amendments to the instant claims do not overcome the rejection, therefore the rejection is maintained.

#### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1, 3, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cao et al. (Analyst (2001) Volume 126, pages 184-188) in view of Kempe (Letters in Peptide Science (2000) Volume 7, page 27-33) in view of Horáček et al. (Analytica Chimica Acta (1997) volume 347, pages 43-50).

The instant claims are drawn to a method of discriminating a peptide that include the steps of providing a derivative of cystine, dissolving the derivative in a mixture of acetonitrile and DMF, absorbing the derivative on a chip to form a single layer, coupling monomers with double bonds and template molecules to the chip to form a molecularly imprinted membrane by polymerization and detecting by a quartz crystal microbalance (QCM) equipped with a flow injection system.

Regarding claims 1, 3, and 6, Cao et al. teach a method that includes absorbing an organic compound on a chip to form a single layer (page 185); coupling monomers with double bonds and template molecules (page 185) to form a molecularly imprinted membrane by polymerization (page 185, right column), and detecting by a quartz crystal microbalance (abstract) and where the organic compound is a peptide (page 185).

However, Cao et al. does not teach using a derivative of cystine and dissolving the derivative in a mixture of acetonitrile and DMF or using a flow injection system.

Regarding claims 1 and 7, Kempe et al. teach using a derivative of cystine and dissolving it in a mixture of acetonitrile and DMF (pages 28-29) as well as using oxytocin as the template molecule (pages 28-29).

Regarding claim 1 and 3, Horáček et al. teaches using a flow injection system (page 46, left column) and derivatives of cystine as a monomer for molecularly imprinted membranes (abstract).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the methods of Cao et al. Kempe and Horáček et al. for the benefit of studying oxytocin in real time. All of the references use molecular imprinted membranes. Horáček et al. method's is drawn to providing a label free method that allows the study of affinity binding in real-time. To accomplish studying the affinity binding in real time, Horáček et al. requires a flow injection system (page 46). To provide for a label free method, Horáček et al. provides a method of binding monoclonal antibodies to a gold substrate that requires derivatives of cystine. Kempe provides MIPS selective for oxytocin for studying oxytocin (page 28) using a derivative of cystine.



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Thus one of ordinary skill in the art would be motivated to combine the methods of Cao et al., Kempe and Horáček et al. to gain the advantage of real time analysis and the ability to bind monoclonal antibodies to a gold substrate for studying oxytocin.

This rejection is necessitated by amendment.

10. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cao et al. (Analyst (2001) Volume 126, pages 184-188) in view of Kempe (Letters in Peptide Science (2000) Volume 7, page 27-33) in view of Horáček et al. (Analytica Chimica Acta (1997) volume 347, pages 43-50) as applied to claims 1, 3, 6 and 7 above, and further in view of Domb (US 5,630,978).

The instant claims are drawn to a method of discriminating a peptide that include the steps of providing a derivative of cystine, dissolving the derivative in a mixture of acetonitrile and DMF, absorbing the derivative on a chip to form a single layer, coupling monomers with double bonds and template molecules to the chip to form a molecularly imprinted membrane by polymerization and detecting by a quartz crystal microbalance (QCM) equipped with a flow injection system, wherein a template molecule is vasopressin.

Cao et al., Kempe, and Horáček et al. are applied as above.

However, Cao et al., Kempe, and Horáček et al. do not teach using vasopressin.

Domb teaches using oxytocin or vasopressin as the template molecule for molecular imprinting (column 10, lines 46-57; and claims 6, 11 and 25).

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the hormone, oxytocin, in the method of Cao et al, Kempe, and Horáček et al. with the hormone, vasopressin, taught by Domb. Domb teaches a method of imprinting molecules to study an array of hormones such as oxytocin or vasopressin (column 10, lines 46-57; and claims 6, 11 and 25). Given that oxytocin and vasopressin are both hormones that may be used similarly in molecular imprinting, one of ordinary skill in the art could have substituted oxytocin for vasopressin and for the predictable results of creating a molecularly imprinted membrane to study vasopressin. This rejection is necessitated by amendment.

### ***Withdrawn Rejections***

11. Applicant's arguments and amendments, filed September 19, 2007, with respect to the rejections made under 35 U.S.C. §103 as being unpatentable over Cao et al. and Horáček et al. and being unpatentable over Cao et al., Horáček et al., and Domb have been fully considered and are persuasive. The combination of these references does not teach the newly added step of dissolving a derivative of cystine in a mixture of acetonitrile and DMF. These rejections have been withdrawn; however, it is noted that Kempe et al. is relied upon for the newly recited limitation, in the rejections above.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00-6:30, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached at (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JL/

/Marjorie A. Moran/  
SPE, AU 1631  
11/16/2007